Journal of Food Law & Policy

Volume 15 | Number 2 Article 6

2019

Science and Risk Analysis in CPTPP/SPS-Plus: Role Model or Unbearable Burden?

Kuei-Jung Ni
National Chiao Tung University

Journal of
FOOD & LAW
POLICY

Volume Fifteen Number Two

Fall 2019

SCIENCE AND RISK ANALYSIS IN CPTPP/SPS-PLUS: ROLE MODEL OR UNBEARABLE BURDEN?

Kuei-Jung Ni

A PUBLICATION OF THE UNIVERSITY OF ARKANSAS SCHOOL OF LAW

Science and Risk Analysis in CPTPP/SPS-Plus: Role Model or Unbearable Burden?*

Kuei-Jung Ni**

Abstract

Trade in food and agricultural products accounts for a major part of global trade, and the trade continues to alert domestic consumers to the risks associated with modern food processing and production methods. The Trans-Pacific Partnership Agreement (TPP), now rebranded as the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), represents a new model of mega-regional trade pacts posed to set higher standards for promoting and streamlining trade liberalization. Because of concerns with national food safety regulations that could constitute forms of non-tariff barriers, the CPTPP, in contrast to the World

* A preliminary draft was delivered at workshops held at the Faculty of Law, Chinese University of Hong Kong, on December 5, 2016, at Edinburgh Law School, on July 20, 2017, and at the School of Law, National Chiao Tung University, on October 18, 2018. The research was partially supported by the Royal Society of Edinburgh that sponsored my visit to the Scottish Centre for International Law during July 9–23, 2017. The author is grateful to Professor Bryan Mercurio, Professor Stephen Neff, Dr. James Harrison, Dr. Filippo Fontanelli, Professor Markus Wagner, Dr. Alice De Jonge, and Dr. Nicola Charwat for their helpful questions and comments. The author thanks Yi-Mei Pan and Chien-Yu Lung for their valuable research assistance. This work was also supported by the Higher Education Sprout Project of National Chiao Tung University and the Ministry of Education, Taiwan.

** Kuei-Jung Ni is Professor of Law and Director of the Center for Trans-Pacific Partnership and Transnational Trade Laws at the School of Law, National Chiao Tung University (NCTU) in Taiwan. He specializes in international economic law, international environmental law, and bio-technology law, especially covering the cross-cutting issues of trade, the environment, and public health. His present study focuses on exploring transnational regulations on food safety and risk analysis, including normative works of competent international regimes, such as the WTO, RTAs, Codex, and the Biodiversity Convention, etc., and examining national implementations and autonomy spaces as well. He has written dozens of articles appearing in trade, environmental, and health law journals. Recent publications include "Food Safety and International Trade" (Angle, 2016); "Compulsory Licensing for Clean Technologies" (World Trade Review, Vol. 14(4), pp. 701-719, 2015); and "Science and Technology in International Economic Law," co-edited with Bryan Mercurio (Routledge, 2014). He was the former Director of the Institute of Technology Law, NCTU, and served as an Acting Dean at the School of Law, NCTU in 2018. In 2013, he was awarded the grant of the Senior Fulbright Research to research food safety law and policy at the Petrie-Flom Center of Harvard Law School. Professor Ni received his Ph.D. in law from the University of Edinburgh, an LL.M from the University of California at Berkeley and an LL.B from the National Taiwan University.

Trade Organization (WTO), stipulates further rules on parties' sanitary and phytosanitary measures (SPS), achieving a type of role model of SPS-plus.

This article explores the legal implications and progressiveness of the SPS-plus design, particularly focusing on the requirements of scientific evidence and risk analysis. The SPS-plus that sets hurdles for national regulatory regimes largely reflects WTO jurisprudence, international health standards, and the national regulations of the United States. I argue that the role model may provide momentum to modernize parties' food safety regimes, but the cost of full compliance could be high. Genuine collaboration, experience-sharing, and technological and financial support between developed countries and less developed countries may alleviate the difficulties of implementation and promote coherence.

Key words: CPTPP, SPS-Plus, Food Safety, Science, Risk Analysis

I. Introduction

Food trade accounts for a major part of global trade, and domestic consumers are increasingly wary of the safety of imported foods. Although food trade can ensure food security for countries that cannot sustain themselves, it may also engender risks that originate from modern food processing and production methods. Therefore, national food authorities are expected to manage food risks cautiously. Risk analysis consists of three components, namely risk assessment, risk management, and risk communication, which has become an important mechanism of risk control.

The incorporation of risk analysis in food regulations has succeeded at global and local levels in ensuring food safety. The Codex Alimentarius Commission (CAC), a World Health Organization (WHO) and Food and Agriculture Organization (FAO) subsidiary, is the leading international food safety institution. The CAC not only engages in risk analysis in setting international food standards, but also promotes the implementation of risk analysis within national regimes.[1] The WHO and the FAO have jointly produced a guidance document to help national authorities establish food safety risk analysis regimes.[2] Nonetheless, the document,

---

[1] CODEX ALIMENTARIUS COMM'N., WORKING PRINCIPLES FOR RISK ANALYSIS FOR FOOD SAFETY FOR APPLICATION BY GOVERNMENTS 2–9 (2007), http://www.fao.org/3/a-a1550t.pdf.

[2] FOOD AND AGRIC. ORG. & WORLD HEALTH ORG., FOOD SAFETY RISK ANALYSIS:

although useful in this regard, is implemented on a voluntary basis. The European General Food Law represents a clear model of the full incorporation of risk analysis in governing food safety,[3] and the Food Safety Basic Law of Japan also recognizes the indispensable role of risk analysis in ensuring consumers' confidence in food safety.[4]

Concerned with the impact of national regulations on imported foods, the World Trade Organization's (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) requires members to adopt risk-based decision-making and especially to link trade measures to risk assessment.[5] However, the drafters of the SPS Agreement did not intend to oblige members to build a thorough risk analysis system into their regulations, despite certain provisions partially reflecting such ideas.[6] Since the WTO Doha Round was in dilemma, trading parties have turned their efforts to negotiating regional trade agreements (RTAs). To further promote the international flow of agricultural products without unjustified intervention, certain SPS-plus disciplines have been pursued.[7] In contrast to the SPS Agreement, most SPS-plus arrangements have emphasized cooperation and effective coordination between parties.[8] Nonetheless, most of the agreements have shown little interest in pushing for the establishment of an advanced system for risk-based regimes beyond that of the WTO's original mechanism.[9]

A GUIDE FOR NATIONAL SAFETY AUTHORITIES xi–xii (2006), http://www.fao.org/docrep/012/a0822e/a0822e00.htm [hereinafter FAO & WHO GUIDE].

[3] Risk Analysis constitutes one of the general principles of European food law of which definition has clearly been provided. *See* 2002 O.J. (L 31) 1–8 (defining Risk Analysis as one of the general principles of European food law) [hereinafter European General Food Law].

[4] FOOD SAFETY COMM'N. OF JAPAN, JAPAN FOOD SAFETY BASIC LAW (2010), http://www.fsc.go.jp/english/brochure/brochure2010/fsc10_p3.pdf.

[5] *See* Agreement on the Application of Sanitary and Phytosanitary Measures, arts. 5.1–5.4, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 493 [hereinafter SPS Agreement].

[6] *Id.* arts. 5.5–5.6.

[7] *See* Part II of this Article and corresponding footnotes.

[8] *See e.g.*, The Comprehensive Economic and Trade Agreement between the European Union and Canada, entered into force provisionally on September 21, 2017, art. 5.4, https://ec.europa.eu/trade/policy/in-focus/ceta/ceta-chapter-by-chapter/ [hereinafter CETA]; *see* also, The Economic Partnership Agreement between the European Union and Japan, signed on July 17, 2018, entered into force on February 1, 2019, art. 6, http://ec.europa.eu/trade/policy/in-focus/eu-japan-economic-partnership-agreement/ [hereinafter Economic Partnership Agreement].

[9] *See id.*

The finalization of the Trans-Pacific Partnership Agreement (TPP) involved many stages of negotiations and partners. It began with plurilateral talks of the Trans-Pacific Strategic Economic Partnership between Brunei, Chile, New Zealand, and Singapore.[10] Subsequently, more Asia-Pacific countries expressed interest in joining the trade block. In particular, the United States' (U.S.) determination to lead and set the agenda for the mega-regional trade arrangement made the TPP the most ambitious and unprecedented RTA in both economic strength and standards.[11] The TPP concluded in 2015 represented a new model of mega-free-trade pacts and was posed to set higher standards for promoting and streamlining trade liberalization,[12] and to espouse significant values beyond trade and commerce concerns.[13]

Since the Trump administration withdrew the U.S. from the TPP in early 2017, the remaining 11 parties have endeavored to keep the agreement alive. During the Trans-Pacific Partnership Ministerial Meeting held in Da Nang, Vietnam, on November 11, 2017, the TPP-11 countries in the Pacific region—New Zealand, Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, Peru, Singapore, and Vietnam—reached a consensus that the TPP would be temporarily replaced by the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP).[14]

---

[10] *See Trans-Pacific Strategic Economic Partnership (P4),* NEW ZEALAND FOREIGN AFFAIRS & TRADE, https://www.mfat.govt.nz/en/trade/free-trade-agreements/free-trade-agreements-in-force/p4/ (last visited Oct. 26, 2019) (discussing the timeline of the Trans-Pacific Strategic Economic Partnership which was signed in 2005 and entered into force in 2006); *see also,* The Trans-Pacific Strategic Economic Partnership (P4), https://www.mfat.govt.nz/assets/FTAs-agreements-in-force/P4/Full-text-of-P4-agreement.pdf.

[11] *See* RAHEL AICHELE & GABRIEL FELBERMAYR, THE TRANS-PACIFIC PARTNERSHIP DEAL (TPP): WHAT ARE THE ECONOMIC CONSEQUENCES FOR IN- AND OUTSIDERS? 4 (2015), http://ged-project.de/2015/10/09/who-wins-and-who-loses-with-tpp/.

[12] *But cf.*, *Free Trade Agreements*, OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, https://ustr.gov/trade-agreements/free-trade-agreements, (last visited Oct. 26, 2019) (indexing the voluminous list of individual trade agreements between the U.S. and other nations).

[13] *See* Press Release, Ministry of Foreign Affairs of Japan, Notification of Completion of Domestic Procedures for the Trans-Pacific Partnership (TPP) Agreement (Jan. 20, 2017), http://www.mofa.go.jp/press/release/press4e_001443.html ("It also seeks to deepen and broaden economic ties among countries and regions that share fundamental values such as freedom, democracy, basic human rights, and the rule of law, and is hence strategically significant in terms of pursuing further regional stability.").

[14] *See* Press Release from Minister Taro Kono, Ministry of Foreign Affairs of Japan, Agreement at the Ministerial Level on the TPP Negotiations Among 11 Countries (Nov. 11, 2017), http://www.mofa.go.jp/press/release/press4e_001788.html.

The CPTPP was signed in Chile on March 8, 2018.[15] The free trade pact would become effective 60 days after at least six (or 50%) of the signatories notified the Depositary (New Zealand) of the completion of ratification procedures.[16] As of October 30, 2018, six countries (Canada, Australia, Japan, Mexico, New Zealand, and Singapore) have ratified the agreement. Therefore, the CPTPP entered into force on December 30, 2018.[17]

Several original commitments of the TPP, including intellectual property and investment Chapters, have been suspended, but the SPS Chapter remains unchanged. Due to concerns that national food safety regulations could constitute a form of non-tariff barriers (NTBs), the CPTPP, in contrast to the WTO, adds further requirements to parties' SPS measures, referred to as SPS-plus.[18] In particular, the CPTPP SPS Chapter explicitly requires risk analysis and provides definitions for its components.[19] In contrast to recent SPS-plus developments in other RTAs and free trade agreements (FTAs), the CPTPP's SPS approach appears unique and ambitious. The effort to push the incorporation of the risk regime into parties' regulatory regimes is a progressive agenda that presents both opportunities and challenges for national compliance.

This article explores the legal implications of the progressive design of the SPS-plus model and assesses its impact, particularly focusing on the requirements of scientific evidence and a risk analysis regime. The difficulty for national regulatory regimes to fulfill such high SPS standards seems apparent, but the mandate may provide an opportunity to modernize national food safety governance that has thus far been subject to political and non-science-based considerations. Part II introduces the development of SPS-plus in RTAs. Part III of this article analyzes the CPTPP's approach to applying a risk analysis mechanism,

---

[15] *See* Dave Sherwood & Felipe Iturrieta, *Asia-Pacific Nations Sign Sweeping Trade Deal Without U.S.*, THOMPSON REUTERS (Mar. 8, 2018, 12:12 AM) https://www.reuters.com/article/us-trade-tpp/asia-pacific-nations-sign-sweeping-trade-deal-without-u-s-idUSKCN1GK0JM.

[16] *See id.*

[17] *See Comprehensive and Progressive Agreement for Trans-Pacific Partnership,* N.Z. FOREIGN AFFAIRS & TRADE, https://www.mfat.govt.nz/en/trade/free-trade-agreements/free-trade-agreements-in-force/cptpp/cptpp-overview/ (last visited Oct. 26, 2019) (discussing the origins of the CPTPP and ratification process).

[18] *See* Comprehensive and Progressive Agreement for Trans-Pacific Partnership, signed on March 8, 2018, entered into force on December 30, 2018, ch. 7, https://www.mfat.govt.nz/assets/Trans-Pacific-Partnership/Text/7.-Sanitary-and-Phytosanitary-Measures-Chapter.pdf [hereinafter CPTPP].

[19] *Id.* arts. 7.1, 7.9.

describes the discrepancy between the WTO contexts and those of the SPS-plus, and explores the implications of the obligations imposed on the parties. Part IV discusses the challenges facing the parties in implementing the added requirements. Part V concludes that the significance and challenges of applying the SPS-plus standards for improving national food risk regulatory regimes are considerable. All parties to the new model of RTA should work in good faith to make the arrangement beneficial to all stakeholders.

II. Developments of SPS-Plus in RTAs

The impasses of the WTO Doha agenda pushed trading parties to pursue further trade liberalization by negotiating RTAs and FTAs.[20] The aims of the free trade zones include, *inter alia*, tariff reduction, trade facilitation, NTB elimination, regulatory cooperation, and anti-corruption and environmental protection provisions.[21] These objectives exceed the original WTO commitments, namely WTO-plus.[22]

When trade partners have pursued WTO-plus at regional and bilateral levels, the premise of SPS-plus has also been included in the negotiations.[23] During the past decade, many RTAs/FTAs have been concerned with increasing NTBs and non-tariff measures (NTMs).[24] Several reasons have made the move increasingly urgent. Public health concerns, particularly for the risks brought by imported agricultural products, have increasingly attracted the attention of national consumers, prompting nations to increase the level of protection concerning health and environmental safety and tighten their regulations.[25] Regulation of imported foods has been enhanced by requiring more inspections and sophisticated certifications. These alleged NTBs or NTMs, many of which have not been entirely science-based or rule-based, have alarmed countries, particularly exporting countries.[26] Such countries have

---

[20] MITSUO MATSUSHITA ET AL., THE WORLD TRADE ORGANIZATION: LAW, PRACTICE, AND POLICY 24–25 (3rd ed. 2016).

[21] *International Free Trade Zone*, ECONOMY WATCH (May 25, 2010), https://www.economywatch.com/international-trade/free-trade-zone.html.

[22] *See* Ken Ash and Iza Lejarraga, *Can We Have Regionalism and Multilateralism? in* TACKLING AGRICULTURE IN THE POST-BALI CONTEXT 75–78 (Ricardo Melédez-Ortiz et al., eds., 2014).

[23] *Id.* at 77.

[24] United Nations Conference on Trade and Dev., NON-TARIFF MEASURES: ECONOMIC ASSESSMENT AND POLICY OPTIONS FOR DEVELOPMENT 4 (2018), https://unctad.org/en/PublicationsLibrary/ditctab2018d3_en.pdf.

[25] *Id.* at 85, 115.

[26] United Nations Conference on Trade and Dev., NON-TARIFF MEASURES IN

argued that SPS-plus should be constructed to prevent the abuse of such measures or the implementation of disguised protectionist policies.[27]

In negotiations of SPS-plus arrangements, parties have pursued some common goals, such as the further elaboration of thorough scientific principles and risk analysis to support and justify food regulations, elimination of unnecessary non-science-based measures, and expansion of the width and depth of information sharing, including transparency requirements.[28] In particular, to facilitate food trade, cooperation and consultation mechanisms have been enhanced.[29] The relevant texts of the CPTPP, the Comprehensive Economic and Trade Agreement between the European Union (EU) and Canada (CETA), and the EU-Japan Economic Partner Agreement (EPA) reflect similar approaches with minor distinctions.[30] In general, these developments derived from a gradual consensus-building among WTO members. Scholars have observed that "many SPS-plus measures found in RTAs are already enshrined in the voluntary guidelines of the WTO SPS Committee on how to implement the WTO SPS Agreement."[31] The mutuality and interdependence of the agreements can help achieve the convergence of regional SPS-plus approaches and multilateral developments. The progress in RTAs thus, as observed, may be expected to promote the multilateralization of such RTA-plus measures.[32]

ASEAN 2, 125 (Lili Yan Ing et al. eds., April 2016), https://unctad.org/en/PublicationsLibrary/ERIA-UNCTAD_Non-Tariff_Measures_in_ASEAN_en.pdf.

[27] Naoto Jinji, *An Economic Theory of the SPS Agreement*, THE RESEARCH INST. OF ECON., TRADE AND INDUS. 1, 3, https://www.rieti.go.jp/jp/publications/dp/09e033.pdf.

[28] RENÉE JOHNSON, CONG. RES. SERV., R43450, SANITARY AND PHYTOSANITARY (SPS) AND RELATED NON-TARIFF BARRIERS TO AGRICULTURAL TRADE 11-12 (2014); *see also,* CETA, *supra* note 8, chs. 4–5; Economic Partnership Agreement, *supra* note 8, chs. 6–7.

[29] Markus Wagner, *The Future of SPS Governance: SPS-Plus or SPS-Minus?* 51 J. WORLD TRADE 445, 461 (2017).

[30] CPTPP, *supra* note 18, chs. 7–8; CETA, *supra* note 8, chs. 4–5; Economic Partnership Agreement, *supra* note 8, chs. 6–7.

[31] Ash & Lejarraga, *supra* note 22, at 77.

[32] *See id.* at 76, 81.

III. Scientific Principles and Risk Analysis in CPTPP/SPS-Plus

A. Overall Approach of the SPS Chapter of CPTPP

The U.S. was influential in shaping SPS-plus regarding scientific principles and risk analysis during original TPP negotiations. The proposal of the Office of the United States Trade Representatives (USTR) transcended the existing rules under the WTO and prior U.S. bilateral/regional trade deals. For example, the USTR intended to clarify the elements of risk assessment that were considered to be inadequately elaborated[33] in the text of Article 5.1 of the SPS Agreement. The USTR's proposal was premised on the concern shared by many exporters that some WTO members adopted import restrictions based on flawed or even nonexistent risk assessments, and, consequently, an "adequate" risk assessment must be further defined. [34] Considering its tensions with several countries in the Asia-Pacific region (Japan, Korea, Taiwan, etc.) regarding certain food safety controversies since 2011, the U.S. anticipated crafting the TPP/SPS Chapter as a mega-regional template for future application.[35] The negotiators consolidated the various SPS proposals into a single text at the ninth round in Chicago, including key elements such as a timeline for risk assessment, enhanced process transparency, and a more specific definition of "sound science."[36]

Subsequently, U.S. agri-food groups started to jointly and publicly make their appeals at the twelth TPP negotiation round in Dallas.[37] Several recommendations aimed at revamping existing SPS rules were proposed, including an elaborate set of risk assessment and risk management requirements, enhanced transparency (notification and explanation of new measures and a reasonable length of time for public comments on draft measures), and an emphasis on international standards and harmonization.[38] These recommendations played a vital role in the subsequent

---

[33] *USTR May Offer Revised SPS Proposal in TPP, Aims to Go Beyond WTO*, INSIDE U.S. TRADE (July 22, 2011), https://wtonewsstand.com/content/ustr-may-offer-revised-sps-proposal-tpp-aims-go-beyond-wto.
[34] *Id*.
[35] *Id.*
[36] *U.S. Tables Revised SPS Chapter, TPP Round Produces Consolidated Text*, INSIDE U.S. TRADE (Sep. 16, 2011), ProQuest Central, Document ID: 911969547.
[37] *Agriculture, Food Industry Seek WTO-Plus Rules for TPP Chapter*, INSIDE U.S. TRADE (May 18, 2012), ProQuest Central, Document ID:1014125823.
[38] *Id.*

rounds of negotiations.

The risk analysis mechanism has been adopted by several international institutions that govern food safety, such as the CAC[39] and the 2001 Biosafety Protocol.[40] Some national and supranational regulatory regimes have also applied and practiced this model, including the EU[41] and Japan.[42]

The WTO SPS Agreement requires compliance with science-based and risk-based principles for adopting national SPS measures.[43] However, the agreement only explicitly mentions the idea of risk assessment and does not specify the terms of risk management and risk communication.[44] The Panel in *EC–Hormones* explained the essence of Article 5 of the SPS Agreement by covering elements of both risk assessment and risk management.[45] The broad approach to align the coverage with the general understanding, however, was rejected by the Appellate Body simply because such a wording of risk management did not explicitly appear in the context.[46]

Regulatory cooperation has constituted one of the major goals of current RTA/FTA negotiations.[47] Such a mandate is also

---

[39] *See* Food and Agriculture Organization [FAO] & World Health Organization [WHO], *Codex Alimentarius Comm'n: Report of the Twenty-Sixth Session*, app. IV, Ref. No. ALINORM 03/41 (June 30 – July 7, 2003), http://www.fao.org/docrep/006/Y4800E/y4800e0o.htm#bm24 (containing the working principles that guide the work of the Commission and its subsidiary bodies regarding risk analysis).

[40] *See* Cartagena Protocol on Biodiversity to the Convention on Biological Diversity, arts. 15–16, annex III, *adopted* Jan. 29, 2000, 2226 U.N.T.S. 208, (entered into force Sept. 11, 2003).

[41] The European General Food Law, *supra* note 3, art. 6.

[42] According to Japan Food Safety Basic Act, "a new concept of 'risk analysis' was introduced to promote food safety in a more comprehensive manner. *See* http://www.fsc.go.jp/english/brochure/brochure2010/fsc10_p3.pdf (last visited Oct. 10, 2018).

[43] SPS Agreement, *supra* note 5.

[44] *See id.* (discussing only risk assessment, without mention of risk management or risk communication).

[45] Panel Report, *European Communities – Measures Concerning Meat and Meat Products (Hormones)*, WTO Doc. WT/DS48/R/CAN, ¶¶ 8.94–8.95, 8.98 (Aug. 18, 1997) [hereinafter Panel Report, EC – Hormones].

[46] Appellate Body Report, *European Communities – Measures Concerning Meat and Meat Products (Hormones)*, WTO Doc. WT/DS26/AB/R, WT/DS48/AB/R, ¶ 181 (Jan. 16, 1998) [hereinafter Appellate Body Report, EC – Hormones].

[47] *See* Alexia Brunet Marks, *The Right to Regulate (Cooperatively)*, 38 U. PA. J. INT'L L. 1, 64-65 (2016) (illustrating a number of RTA/FTA practices in enhancing regulatory cooperation, particularly on SPS matters); *see generally* Eugenia Costanza Laurenza & Fabienne Goyeneche, *Regulatory Cooperation in Free Trade*

commonly required in many SPS Chapters of trade agreements. For example, CETA reflects the trend.[48] The EPA also highlights the significance of cooperation for easing possible health-related regulatory disagreements.[49] Both agreements, despite being negotiated by parties of developed countries, failed to elaborate a risk regime beyond the original WTO/SPS design in the end. The EPA—irrespective of its ambition to consolidate risk analysis, as evidenced in an early EU assessment report[50]—has turned out to be a simple repetition of the WTO legacy.[51]

By contrast, the CPTPP SPS Chapter has unequivocally specified the requirement for risk analysis.[52] It is the first attempt at incorporating a relatively sound risk-based and science-based mechanism into a regional trade regime.[53] The unprecedented approach is a clear indication of the original vision of the U.S. in seeking the codification of high standards into SPS-plus. The effort also represents a progressive development in the WTO/SPS arrangement.

The U.S. has withdrawn itself from the TPP, but the approach originally proposed by the U.S. continues to impact on its current RTA negotiations. The North America Free Trade Agreement (NAFTA) between the U.S., Mexico, and Canada has been renegotiated since the Trump administration came into office.[54] This RTA has been replaced by the newly-concluded United States–Mexico–Canada Agreement (USMCA).[55] Some

---

Agreements: Perspectives from the Automotive and Information and Communication Technology Sectors, 12 GLOBAL TRADE AND CUSTOMS J. 433 (2017) (discussing the forms of regulatory cooperation and their use in modern free trade agreements, particularly in the automotive industry and information and communication technology sectors).

[48] CETA, *supra* note 8, arts. 21.1– 21.2.

[49] *See* Economic Partnership Agreement, *supra* note 8, art. 6.1.

[50] *See* LSE ENTER., TRADE SUSTAINABILITY IMPACT ASSESSMENT OF THE FREE TRADE AGREEMENT BETWEEN THE EUROPEAN UNION AND JAPAN 59–60 (2015).

[51] *See* Economic Partnership Agreement, *supra* note 8, arts. 6.4, 6.6 (reiterating the mandate of the WTO SPS Agreement on risk assessment).

[52] CPTPP, s*upra* note 18, art. 7.9.

[53] Because the U.S and other countries have a strong comparative advantage in agricultural production, they consider import restrictions should meet more reasonable and sound scientific tests to avoid NTBs. *See* notes 33–37 and accompanying text.

[54] The USMCA was concluded on Sep. 30, 2018. *See* Alan Rappeport, *A Last-Minute Deal With Canada Salvages a Trade Agreement*, N.Y. TIMES, Oct. 1, 2018, at A1 https://www.nytimes.com/2018/09/30/us/politics/us-canada-nafta-deal-deadline.html (last visited October 31, 2018).

[55] *Id.*

changes in the new trade deal originated from the TPP *per se*.[56] In terms of the SPS rules, the USMCA maintains a large portion of the TPP ingredients.[57] The provision concerning "science and risk analysis" generally mirrors that of the TPP/SPS with minor modifications.[58]

B. Implications and Progress of Risk Analysis in the CPTPP/SPS Chapter

i. General Idea of Risk Analysis in the CPTPP

The CPTPP's definition of risk analysis[59] reflects the common usage appearing at international, regional, and national levels.[60] In particular, it increases the requirements for the format of risk analysis and public involvement in the process by requiring that the operation of the system be documented and opportunities for public comment be provided to interested persons or parties.[61] To clarify the application, the SPS Chapter specifies that such requirements apply only to a risk analysis for a sanitary or phytosanitary measure that constitutes a sanitary or phytosanitary regulation for the purposes of Annex B of the SPS Agreement (transparency).[62]

In the pursuit of harmonization, the WTO/SPS Agreement expects members to apply international standards, guidelines, and recommendations and extends certain incentives,[63] but such international standards are not binding on WTO members *per se*.[64]

---

[56] *See* Justin Worland, *Trump's NAFTA Replacement Largely Maintains Status Quo on Free Trade*, TIME (Oct. 1, 2018), https://time.com/5411444/nafta-trump-deal-usmca/.

[57] *Id.*

[58] In contrast to the CPTPP, the new agreement replaces risk analysis with risk assessment and risk management, although the title of the provision remains unchanged. The move may indicate the USMCA's intent to reduce the mandate of risk communication. Agreement between the United States of America, the United Mexican States, and Canada art. 9.6, U.S.-Mex.-Can., Nov. 30, 2018; *see also* CPTPP, s*upra* note 18, art. 7.1.

[59] *Id.* art. 7.1.

[60] FAO & WHO GUIDE, *supra* note 2, at 7; *see also* European General Food Law, *supra* note 3, art. 3, paras. 11-13.

[61] CPTPP, *supra* note 18, art. 7.9.

[62] *Id*. footnote 4 to art. 7.9, ¶ 4(b).

[63] Article 3.2 of the SPS Agreement provides that national SPS measures that conform to international standards enjoy the presumption of consistency with the SPS Agreement. SPS Agreement, *supra* note 5, at 2.

[64] Observing the Appellate Body's jurisprudence has led to the conclusion that "[t]he Appellate Body's interpretation . . . has turned the course of subsequent SPS

The WTO case law has not fully recognized a principle of deference to certain international standards and their setting. In *Hormones II*, the Appellate Body departed from international standard-setting in two main aspects. First, the Appellate Body opined that experts involved in standard-setting may lack independence and not be suitable to provide objective opinions, especially if they were not in agreement with members who sought a higher level of protection than that of an international regime.[65] Second, it also rejected the idea that an existing international standard can justify the sufficiency of scientific evidence that may disqualify a provisional measure.[66]

By contrast, the TPP negotiators managed to bring the SPS Chapter closer to international standard-setting and demonstrated an intent to further the mandate of harmonization by, *inter alia*, including the encouragement of "the development and adoption of international standards, guidelines and recommendations" and the promotion of "their implementation by the Parties" as one of the objectives of the SPS Chapter.[67] The text was aimed at making enforceable the relevant international arrangements on risk analysis that are usually voluntary. As the WTO/SPS Committee and other international standard-setting regimes, including the WHO and FAO, have provided useful references for building a risk analysis regime, the CPTPP parties are required to take into account their works in designing their regulations.[68] In effect, the CPTPP SPS Chapter bluntly reinforces the relevance of international soft law with the establishment of a national risk analysis regime.

---

jurisprudence away from the assessment of national SPS measures against international benchmark standards." *See* JACQUELINE PEEL, SCIENCE AND RISK REGULATION IN INTERNATIONAL LAW, 178–81(2010).

[65] Appellate Body Report, *United States – Continued Suspension of Obligations in the EC – Hormones Dispute*, ¶ 481, WTO Doc. WT/DS320/AB/R (adopted Oct. 16, 2008) [hereinafter Appellate Body Report, U.S. – Continued Suspension]; *see also* KUEI-JUNG NI, *Does Science Speak Clearly and Fairly in Trade and Food Safety Disputes? The Search for an Optimal Response of WTO Adjudication to Problematic International Standard-Making*, 68 FOOD & DRUG L. J. 97, 111–13 (2013) (observing the tendency of the Appellate Body of not entirely endorsing international standard-setting).

[66] The Appellate Body also denied that an existing international standard can entail and prove sufficiency of scientific evidence in order to disqualify a provisional measure. Appellate Body Report, U.S. – Continued Suspension, *supra* note 65, ¶¶ 695,733.

[67] CPTPP, *supra* note 18, art. 7.2, ¶ (f).

[68] *Id.* art. 7.9, ¶ 6(a).

ii. Scientific Principles and Risk Assessment

The SPS Chapter does not provide a new definition of risk assessment as the WTO/SPS Agreement has defined the term clearly.[69] To justify the results of a risk assessment and gain public confidence, many national practices have adhered to certain core values and principles when completing the assessment. For example, the European General Food Law specifies that "[r]isk assessment shall be based on the available scientific evidence and undertaken in an *independent, objective and transparent* manner."[70] The Japan Food Safety Basic Law[71] details similar requirements.[72]

The WTO/SPS Agreement has yet to add further mandates such as those of the EU and Japan. In addition to requiring a science-based approach to risk assessment, it may be desirable for the SPS Chapter to incorporate objectives compatible with higher values such as democracy and fairness. The CPTPP context has not explicitly recognized the principles of independence and transparency. However, as mentioned, the CPTPP parties *shall take into account* international standards, guidelines, and recommendations in the execution of risk analysis.[73] Thus, the WHO and FAO's guidance that recognizes the characteristics of objectivity and transparency in risk assessment[74] may help shape the progress of national risk analysis regimes, although it is of a less obligatory nature.

Article 2.2 of the WTO/SPS Agreement specifies the science-based principle as one of its controlling mandates.[75] According to Article 5.1 of the Agreement, WTO members shall base their trade measures on an assessment of risks.[76] In the assessment of risks, they are required to take into account "available" scientific evidence.[77] In *EC—Hormones*, the Appellate Body stated that these two provisions should be read together.[78] The difference between the WTO/SPS and the

---

[69] SPS Agreement, *supra* note 5, Annex A, ¶ 4.
[70] The European General Food Law, *supra* note 3, art. 6, ¶ (2) (emphasis added).
[71] Japan Food Safety Basic Act, Act No. 48, arts. 13(emphasis added) of May 23, 2003, http://www.fsc.go.jp/english/basic_act/fs_basic_act.pdf.
[72] *Id.* arts. 13, 32.
[73] CPTPP, *supra* note 18, art.7.9, ¶ 6 (a) (emphasis added).
[74] FAO & WHO GUIDE, *supra* note 2, at 48, 49.
[75] SPS Agreement, *supra* note 5, art. 2.2.
[76] *Id.* art. 5.1.
[77] *Id.* art. 5.2.
[78] Appellate Body Report, EC – Hormones, *supra* note 46, ¶¶ 177, 180.

CPTPP/SPS context lies in the benchmark that they set for the eligibility of scientific evidence. The main addition of the SPS-plus in this regard is a focus on making the scientific approach more stringent. A careful reading of the SPS Chapter suggests that it adds criteria of what constitutes "sound science" as opposed to "junk science."

First, regarding the quality of scientific evidence, the SPS Agreement does not classify the type of science that can satisfy the requirement to support a given measure.[79] However, WTO jurisprudence appears to value the significance of scientific robustness.[80] In *US/Canada—Continued Suspension*, the Appellate Body stated that the standard of review exercised by a Panel on a party's risk assessment should involve examining "whether that risk assessment is supported by coherent reasoning and *respectable scientific evidence* and is, in this sense, objectively justifiable."[81] Thus, such science should be examined by a test of whether it "comes from a *respected and qualified* source" and meets "the necessary scientific and methodological rigor."[82] The SPS Chapter adds an element by emphasizing the "objectiveness" of the science to justify an SPS measure in question.[83] The further elaboration and incorporation of the WTO's judicial rulings on qualified science by the CPTPP tighten the admissibility of science for legitimate use in risk assessment. Indeed, the reinforced threshold of requiring legitimate science squarely fulfills the original objective of the TPP negotiations to pursue high standards.

Second, with respect to the form of the scientific evidence in question, neither the WTO/SPS context nor its case law requires any certain format. The CPTPP Chapter states that such scientific evidence must be documented.[84] This requirement raises the threshold of compliance. Nevertheless, given the lack of a clear definition of documentation, it remains unclear how stringent the element should be. An argument that scientific evidence must be published in journals could be too restrictive, given many studies and surveys have yet to be published.[85]

---

[79] SPS Agreement, *supra* note 5, art. 5.2.
[80] *See* PEEL, *supra* note 64, at 190–230 (discussing the WTO's treatment of scientific principles).
[81] Appellate Body Report, US – Continued Suspension, *supra* note 65, ¶ 590.
[82] *Id.* ¶ 591.
[83] CPTPP, s*upra* note 18, art. 7.9, ¶ 2.
[84] *Id.* art. 7.9, ¶ 4(b).
[85] FAO & WHO GUIDE, *supra* note 2, Box 3.9, at 50 (noting that certain

Third, regarding the scope of scientific evidence, the WTO/SPS Agreement simply provides that members are required to apply scientific evidence that is available to them.[86] Given that countries possess various levels of scientific and technological development, the alleged "availability" of the evidence in question may differ. The negotiators of the CPTPP SPS Chapter would likely not be satisfied with the WTO mandate because this approach may, to some extent, exempt members from using the best science that exists worldwide but may not be available in the country under complaint. The SPS Chapter limits the scope of the science in question. It first states that the availability of science to parties shall be "reasonably" available.[87] The additional requirement of reasonableness may impose burdens on parties to perform more searches and surveys for further evidence if to do so would be reasonable. Moreover, parties are required to take into account data that is "relevant."[88] Thus, the limitation could further constrain nations' discretion in data collection.

On the other hand, the CPTPP's approach is also a manifestation of the incorporation of the WTO case law. In *EC—Hormones*, the Appellate Body ruled that the methodology for performing scientific risk assessment is not limited to the usual model of quantitative usage, as a qualitative approach would also be acceptable.[89] Thus, the SPS Chapter aligns with the approach by explicitly covering these two methods.[90]

As expected, the justification for formulating a relatively rigid mandate for the quality of science is not without objections or open questions. The introduction of the idea of "documented and objective science" could narrow down the flexibility of parties to select and apply applicable science. Concerns have been expressed regarding whether the flexibility of using "minority

---

information and data produced by industry may not be published, which nevertheless can be relied on for risk assessment).

[86] SPS Agreement, *supra* note 5, arts. 5.2, 5.7.

[87] CPTPP, s*upra* note 18, art. 7.9, ¶ 5.

[88] *Id.*

[89] The broad understanding was also confirmed by the subsequent rulings. *See* Appellate Body Report, *Australia – Measures Affecting the Importation of Salmon,* WTO Doc. WT/DS18/AB/R, ¶ 124 (Oct. 20, 1998) [hereinafter Appellate Body Report, Australia – Salmon]; Appellate Body Report, U.S. – Continued Suspension, *supra* note 65, ¶ 530; Appellate Body Report, *Australia – Measures Affecting the Importation of Apples from New Zealand,* WTO Doc. WT/DS367/AB/R, ¶ 208 (Nov. 29, 2010) [hereinafter Appellate Body Report, Australia – Apples].

[90] CPTPP, *supra* note 18, art. 7.9, ¶ 5.

science" as recognized by WTO jurisprudence could be undermined by the rigid approach.[91] According to the Appellate Body's rulings, WTO members are permitted to use minority views of the scientific community as the basis for decision-making as long as such views originated from qualified and respected sources.[92] The question thus becomes whether a minority opinion that, despite being reputable, was not formally published or is just the result of "a small number of peer-reviewed studies"[93] could be permissive under the high standard. This may depend on the interpretations of "documentation" for science.

iii. Risk Management

As mentioned, risk management is not explicitly recognized in the WTO/SPS Agreement.[94] Nevertheless, the Agreement reflects certain elements of risk management in the allocation of the rights and obligations of WTO members.[95] For example, Article 5.4 of the SPS Agreement recognizes the right of countries to decide their appropriate level of protection (ALOP),[96] which constitutes a preliminary process of risk management.[97] The Agreement further includes the mandates of necessity and non-discrimination in applying SPS measures.[98] Of course, reflecting a precautionary principle or approach, the Agreement recognizes members' discretion to adopt provisional SPS measures where scientific evidence is insufficient.[99]

---

[91] Wagner, *supra* note 29, at 454.

[92] Appellate Body Report, U.S. – Suspension, *supra* note 65, ¶ 591; Appellate Body Report, Australia – Apples, *supra* note 89, ¶ 214; Appellate Body Report, EC – Hormones, *supra* note 46, ¶ 194.

[93] Wagner, *supra* note 29, at 454–55.

[94] Appellate Body Report, EC – Hormones, *supra* note 46, ¶ 181.

[95] *E.g.* MATSUSHITA *ET AL.*, *supra* note 20, at 475–76.

[96] *See* Australia – Salmon, *supra* note 89, ¶ 199. The Appellate Body also considered that the SPS Agreement also implied an "obligation" of WTO members to disclose their ALOP precisely. *Id.* ¶ 206. The WHO and FAO Guide specifies that the determination of an ALOP is critical when the selection of a risk management option is undertaken. *See* FAO & WHO GUIDE, *supra* note 2, at 29–31.

[97] MATSUSHITA *ET AL.*, *supra* note 20, at 486 (citing Appellate Body's ruling on Australian Salmon).

[98] SPS Agreement, *supra* note 5, arts. 5.5, 5.6.

[99] *See* Appellate Body Report, EC – Hormones, *supra* note 46, ¶ 124 (recognizing that Article 5.7 reflects the idea of precaution without confirming whether it is a principle or an approach).

The CPTPP/SPS Chapter continues to extend certain regulatory autonomy to parties relating to risk management. It affirms the right of parties to establish their ALOP[100] and preserves the right to implement SPS measures on a provisional basis.[101] Concerning the obligations of parties conducting risk management, apart from reiterating the non-discrimination principle, the SPS adds, most notably, a procedural mandate requiring that risk management be conducted in a documented manner.

The SPS Chapter defines risk management as "the weighing of policy alternatives in light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures."[102] This definition is quite similar to the general understanding of risk management found in the European General Food Law[103] and WHO/FAO documents alike.[104]

The SPS Chapter contributes to the legalization of risk management by incorporating international institutions' efforts relating to risk management. For example, the WHO and FAO produced a guidance document for helping national food safety authorities to establish their risk analysis regime.[105] This document provides a generic four-step framework for risk management: (i) preliminary risk management activities; (ii) identification and selection of risk management options; (iii) implementation; and (iv) monitoring and review.[106] The CPTPP parties are required to "take into account" such arrangements.[107] The framework remains non-binding on parties,[108] but its incorporation to some extent may compel the revamping of national regulatory structures. Building a regime and framework not only requires rule-making and legislative efforts but also demands substantial expertise, management skills, financial resources, and capacity-building. The attempt to push the modernization of risk

---

[100] CPTPP, *supra* note 18, art. 7.9, ¶ 3(a).
[101] *Id.* art. 7.9, ¶ 3(c).
[102] *Id.* art. 7.9, ¶ 2.
[103] European General Food Law, *supra* note 3, art. 3, ¶ 12.
[104] FAO & WHO GUIDE, *supra* note 2, at 7.
[105] *See id.*
[106] *Id.* at 11, 15–35.
[107] CPTPP, s*upra* note 18, art. 7.9, ¶ 6(a) (emphasis added).
[108] *See* FAO & WHO GUIDE, *supra* note 2, at xii (The Guide "provides essential background information, guidance and practical examples of ways to apply food safety risk analysis.") Since the Guide is not of treaty format, it is not binding on nations *per se*.

management systems is indicative of the CPTPP's ambition to set a new model for RTAs.

The SPS Chapter also requires parties to "consider" and "select" risk management options that are not more trade restrictive than necessary to achieve their ALOP and SPS objectives.[109] The CPTPP text seems quite similar to that of WTO/SPS[110] and reaffirms the principles of necessity and proportionality.[111] Nonetheless, the arrangement literally reflects the WHO and FAO's procedure for deciding among risk management options, which involves a dynamic process of identification, evaluation, and selection of risk management options.[112] As mentioned, the SPS Chapter, like the WTO SPS Agreement, reaffirms the right of parties to determine their ALOP; however, both texts fail to clearly describe how ALOP can fairly function. By requiring the CPTPP parties to consider international guidelines, the WHO and FAO's arrangements may help optimize competent national regimes.

When considering and selecting policy options, national authorities are normally expected to determine which level of protection is ideal and suitable for addressing specific food safety issues and risks. The work of the WHO and FAO has helped to clarify the status of ALOP by underscoring that "[t]he concept of ALOP . . . is essential in establishing the linkage between risk management actions and the level of consumer health protection achieved."[113] It also provides that "[a] range of tools or approaches are available to the risk manager in bridging between practical control measures and [the] level of consumer health protection."[114] With the availability of a clearer road map on which regulatory regimes can be based, the predictability and transparency of the process can be enhanced.

Overall, the influence of the international guidelines over the establishment of national regimes cannot be overemphasized. The original voluntary nature of these guidelines has to some extent

---

[109] CPTPP, s*upra* note 18, art. 7.9, ¶ 6(b),(c) (emphasis added).
[110] SPS Agreement, *supra* note 5, art. 5.6.
[111] *Id.*
[112] FAO & WHO GUIDE, *supra* note 2, at 24–33 ("Harmonized and transparent application of a RMF to identify and select risk management options in different countries should significantly advance the goal of preventing unjustified and unfair restrictions in the international trading of food.")
[113] *Id.* at 30.
[114] *Id.*

been hardened by the CPTPP. However, it remains to be seen whether the requirements will limit the parties' regulatory space in constructing their own best regimes per respective risk perceptions. Thus, the one-size-fits-all approach may continue to be of concern for its legitimacy.

iv. Risk Communication

The SPS Chapter defines risk communication as "the exchange of information and opinions concerning risk and risk-related factors between risk assessors, risk managers, consumers and other interested parties," which is also in line with the widely recognized concept.[115] In contrast to its provisions on risk assessment and risk management, the Chapter does not provide any specific requirements or obligations for parties to observe in doing risk communication.[116] Nevertheless, as mentioned, the SPS Chapter mandates that relevant international documents play a major role in guiding national risk analysis.[117] According to the WHO and FAO guidelines, the subject of risk communication involves multiple stakeholders, including risk assessors, risk managers, and external participants.[118] Food authorities expect to form a unit with specialists responsible for communication, which could be integrated into "all phases of risk analysis" by their regulations.[119] Indeed, many developed countries, including the CPTPP parties, have already implemented this task by setting up a specialized team for communication.[120]

The WTO/SPS Agreement did not explicitly stipulate risk communication nor any requirements for the process. However, Article 7 of the Agreement concerning transparency is a major mechanism by which the communication mandate can be fulfilled.[121] WTO members are required to notify other members of their SPS measures and to keep them updated concerning

---

[115] CPTPP, s*upra* note 18, art, 7.1, ¶ 2; *see also* FAO & WHO GUIDE, *supra* note 2, at 66; *see also* European General Food Law, *supra* note 3, art. 3, ¶ 13.
[116] *See* CPTPP, *supra* note 18.
[117] *Id.* art. 7.9, ¶¶ 2, 6(a).
[118] FAO & WHO GUIDE, *supra* note 2, at 66.
[119] *Id.* (emphasis added).
[120] For example, the Japan Food Safety Commission is composed of seven commissioners, including one who has expertise in risk communication. *See, e.g.*, FOOD SAFETY COMMISSION OF JAPAN, *fsc.go.jp/english/aboutus/members_com.html* (last visited Oct. 25, 2019).
[121] SPS Agreement, *supra* note 5, art. 7.

newly-implemented regulations.[122] Annex B, regarding transparency in the WTO/SPS Agreement, provides a more detailed process for communicating information.[123]

Achieving greater transparency in the decision-making process has become a commonly-pursued agenda in current RTA/FTA negotiations. Both the CETA[124] and EPA[125] aimed to improve the quality of transparency for SPS measures. In terms of trade in agricultural products, the deficiency of transparency that constitutes a type of NTB has more direct and stronger effects than a tariff does.[126] Thus, the efforts of the RTA were acclaimed because they were credited with "introducing new obligations that strengthen the *ex-ante* and *ex-post* transparency requirements related to the design and application of standards and establishing improved web-based information systems and consultation processes that include interested foreign parties."[127]

In line with the developments, the CPTPP SPS Chapter elaborates and enhances the level and contingency of transparency.[128] An apparent discrepancy between the WTO SPS arrangement and that of the CPTPP is that the former largely entails one-way communication from national authorities to other members, whereas the latter strengthens mutual understanding and information exchange among governments and relevant stakeholders.

The CPTPP Chapter also endeavors to improve the notice and comment procedure, which may strengthen the input of outward advice. The attempt reflects the administrative practice[129] of the U.S. and was one of the main negotiation pieces put forward by the country.[130] The Chapter provides more stringent requirements on the time for comments and how the parties proposing SPS measures shall interact with their counter-parties.

---

122 *See id.*
123 *See id.* Annex B.
124 CETA, *supra* note 8, ch. 5, arts. 5.11–5.12.
125 Economic Partnership Agreement, *supra* note 8, ch. 6, arts. 6.11, 6.12, 6.15; ch. 17.
126 *See* Ash & Lejarraga, *supra* note 22, at 80–81.
127 *Id*. at 80.
128 CPTPP, *supra* note 18, art. 7.13.
129 Administrative Procedure Act, 5 U.S.C. 553 (2016); s*ee also* Wagner, *supra* note 29, at 464–65 (discussing the merits and problems of incorporating such a practice).
130 *See* JOHNSON, *supra* note 28.

The WTO/SPS Agreement only requires a "reasonable" time for members to make comments.[131] By contrast, the SPS Chapter specifies a fixed time of at least 60 days.[132]

The methods of discussion and communication among parties under the CPTPP arrangements are relatively more proactive than reactive.[133] The required exchanges are more comprehensive and meaningful. WTO members must "discuss these comments upon request, and take the comments and the results of the discussions into account."[134] The SPS Chapter strengthens the interaction by adding that "on request of another Party, the Party *shall respond to* the written comments of the other Party in an appropriate manner."[135] Because the SPS Agreement only requires members to exchange opinions on "comments," the content of the discussion has also been elaborated in the Chapter to include "any scientific or trade concerns" raised by other parties and "the availability of alternative, less trade-restrictive approaches for achieving the objectives of the measure."[136]

If parties' SPS measures are not in conformance with international standards, the SPS Chapter furthers the scope and content of the notification. These countries are obliged to provide more thorough information, which has not been specified under the WTO agreement, such as documented and objective scientific evidence.[137]

The SPS Agreement only suggests that WTO "members" can benefit from the merit of transparency.[138] The CPTPP in particular aims to ensure that the general public is entitled to access the information in question, including the proposed measure, the legal basis for the measure, and the written comments received by the party.[139] Therefore, if implemented appropriately, the design may help promote the realization of democratic decision-making by

---

131 SPS Agreement, *supra* note 5, Annex B, ¶ 5(d).
132 CPTPP, *supra* note 18, art. 7.13, ¶ 4.
133 Ragnar E. Lofstedt, *Risk versus Hazard—How to Regulate in the 21st Century*, 2 EUR. J. RISK REG. 149, 166-67 (2011) (describing how proactive risk communication can achieve better public trust compared to reactive communication).
134 SPS Agreement, *supra* note 5, Annex B, ¶ 5(d).
135 CPTPP, *supra* note 18, art. 7.13, ¶ 4 (emphasis added).
136 *Id.* art. 7.13, ¶¶ 4, 7.
137 *Id.* art. 7.13, ¶ 6.
138 SPS Agreement, *supra* note 5, Annex B, ¶¶ 5, 6.
139 CPTPP, *supra* note 18, art. 7.13, ¶ 5.

bound parties.

The CPTPP's approach is not entirely novel, but rather, reflects international and certain national practices. Nevertheless, its progressiveness distinctive from the WTO SPS Agreement is quite obvious and meaningful. The policy that places parties' trading partners, interested persons, and the general public in beneficial positions may result in a more open, reasonable, non-arbitrary, and democratic decision-making process.

IV. Problems and Challenges with Implementing the SPS-Plus Requirements

The SPS Chapter exhibits a strong intent to incorporate a risk analysis regime into national SPS regulations. Requiring the provision of solid scientific evidence to justify their measures could impose considerable burdens on less developed countries. Some of them may face difficulties in accessing the necessary science and technology. They may not be able to comprehend recent relevant data. It seems too onerous to expect them to have the same level of science and technology rigor as those CPTPP-developed parties. Given these scientific gaps, the implementation problem cannot be ignored.

Many CPTPP parties that are strong in agricultural exports, such as New Zealand, Canada, and Australia, would benefit from importing countries making a real commitment to and enforcing science-based SPS measures. These developed countries have already established relatively sound risk analysis regimes[140] and may have no trouble implementing the mandate.[141] Japan, which

---

[140] For example, Health Canada's Food Directorate has a mandated responsibility to perform health risk assessments in response to requests from the Canadian Food Inspection Agency as laid out in the Memoranda of Understanding and Agreements between Health Canada and the Canadian Food Inspection Agency. *See, e.g.*, *About Health Canada*, GOV'T OF CANADA, https://www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/health-products-food-branch/food-directorate.html.

[141] The New Zealand government stated that "nothing in the SPS Chapter would require New Zealand to change our approach to protecting human health, maintaining food safety, and protecting New Zealand's animal and plant health status from pests and diseases. As a result, there are no disadvantages to New Zealand entering CPTPP from an SPS perspective." *See, e.g.*, N.Z. FOREIGN AFFAIRS & TRADE, COMPREHENSIVE AND PROGRESSIVE AGREEMENT FOR TRANS-PACIFIC PARTNERSHIP NATIONAL INTEREST ANALYSIS 33 (2018), https://www.mfat.govt.nz/assets/CPTPP/CPTPP-Final-National-Interest-Analysis-8-March.pdf.

has tended to fill the leadership vacuum caused by the departure of the U.S., has confidence in ensuring compliance with the risk analysis standards.[142]

Achieving the sound operation of a risk analysis regime always involves a costly and time-consuming process of capacity building. Many less developed countries in this region may face hurdles in overcoming the challenges. Moreover, some competent national food safety regimes have yet to mature.[143] If little or no sound science can be produced to justify trade restrictions, these importing countries have little choice but to adhere to international standards[144] that may not always accommodate their specific public health concerns. The high standard of the CPTPP may also dissuade countries from seeking accession to the agreement if the cost of compromising their policy freedom proves unaffordable.[145]

All parties should work together to mitigate the problem of "technoimperialism," that seeks to impose the high standards of developed countries upon less developed countries without meaningful input from the latter.[146] Assisting these countries in adapting to the stricter regulatory requirements is also indispensable. International regulatory cooperation can play a critical role in promoting coherence and harmonization of regulations and practices among parties.[147] Regarding risk assessment, regulatory cooperation can cover "dialogue, information sharing, and scientific fact-finding" and be fulfilled "by examining the science behind various regulatory approaches and determining which approach aligns with prevailing scientific knowledge."[148] Given that risk management is a relatively subjective process involving

---

[142] Interview with Japanese officials responsible for food safety on September 6, 2016 (on file with the author).

[143] According to the USDA's study, Vietnam's "regulatory and food safety regime is still in its infancy and testing agencies are limited, leading to inconsistent enforcement which adds to uncertainty for foreign producers." *See* U.S. DEP'T OF AGRIC., VIETNAM'S AGRI-FOOD SECTOR AND THE TRANS-PACIFIC PARTNERSHIP 14 (2014), https://www.ers.usda.gov/webdocs/publications/43899/49392_eib130.pdf?v=0.

[144] *See* CPTPP, s*upra* note 18, art. 7.9, ¶ 2.

[145] Despite having signed the CPTPP, it remains unclear whether Malaysia may eventually ratify the agreement, and this is because the high standards may constrain its regulatory autonomy. *See* Martin Khor, *Should Malaysia Ratify the CPTPP Deal?*, THE STRAITS TIMES, (Aug. 13, 2018), https://www.straitstimes.com/asia/se-asia/should-malaysia-ratify-the-cptpp-deal-the-star-columnist?.

[146] Marks, *supra* note 47, at 62–63 (illustrating that TPP may have fostered technoimperialism).

[147] *Id*. at 14–15.

[148] *Id*. at 45–46.

policy-making, regulatory cooperation may not necessarily be feasible.[149]

The CPTPP does provide mechanisms to facilitate regulatory cooperation. The SPS Chapter requires the establishment of a Committee on Sanitary and Phytosanitary Measures.[150] Apart from enhancing the implementation of the Chapter, this Committee is tasked with promoting cooperation between parties through which information exchange can occur. However, the task of engaging in technical assistance and cooperation projects remains optional.[151] Additionally, the CPTPP creates a new chapter on regulatory coherence in which regulatory cooperation and capacity building are given as mandates.[152] A Committee on Regulatory Coherence will be established[153] to supervise regulatory cooperation[154] that "may" include "information exchanges, dialogues or meetings with other Parties and interested persons, training programmes and relevant assistance, and other activities between regulatory agencies."[155] It remains to be seen whether the soft commitment to technical and other substantial support can effectively relieve the less developed countries' burden.

Overall, the CPTPP's ambition to optimize national SPS regulations cannot be fulfilled without genuine collaboration, experience-sharing, and technological and financial assistance.[156] The full realization of the SPS-plus goals will, to some extent, depend on the goodwill and actions of the CPTPP parties that possess sufficient capacities.

V. Concluding Remarks

The requirement for building a sound risk analysis regime is indicative of the CPTPP's pursuit of high standards in food safety

---

149 *Id*. at 45–47.
150 CPTPP, *supra* note 18, art. 7.5, ¶ 1.
151 *Id.* art. 7.5, ¶ 3(e).
152 CPTPP, *supra* note 18, art. 25.2, ¶¶ 1, 2(e); *see also* Marks, *supra* note 47, at 58 (stating that the CPTPP is the first trade agreement to include regulatory coherence).
153 CPTPP, *supra* note 18, art. 25.6, ¶ 1.
154 *Id*. art. 25.6, ¶¶ 2, 4; art. 25.9, ¶¶ 1, 4.
155 *Id.* art. 25.7, ¶ 1 (emphasis added).
156 *See, e.g*., Phoenix X. F. Cai, *Regulatory Coherence and Standardization Mechanisms in the Trans-Pacific Partnership*, 5 BR. J. AM. LEG. STUDIES 505, 537-38 (2016) (observing that the efforts of capacity building can ensure the success of regulatory coherence and cooperation).

regulations. The substance of the risk analysis is a blend of WTO jurisprudence, international standards, and national practices, especially those of the U.S. Observing how this RTA's proposed mechanism may interact with the relevant law-making of the WTO and thus enable the multilateralization of RTA-plus is appealing.[157] The influence of CPTPP's model of risk analysis could be strong upon the parties' will to cooperate and act in good faith.

This lofty regulatory requirement may not be difficult to meet for some parties, such as Japan, Australia, and Canada. However, given the complexity of the system and the necessity for major capacity building and interdisciplinary professions, it would be undesirable for less developed countries to be required to attain the same level as countries that have substantial experience and practice in this regard.

The requirement of scientific risk assessment does raise the level for admissible scientific evidence. It would place the science used by the parties under scrutiny. Nonetheless, the credibility of scientific findings would not be subject to dispute settlement under the CPTPP, which can thus reduce the pressure on the parties, leaving them some leeway vis-à-vis regulatory space and autonomy.

Many Asian countries face the challenge of balancing the promotion of food trade with the protection of citizens from the risks engendered by imported food. For example, Korea and Taiwan have prohibited the import of potentially radioactive foods from Fukushima, Japan, for many years. Although the food risks have gradually decreased, those countries are still hesitant to lift the ban, and this is not necessarily only because of health concerns but also for social or political reasons. However, if the risk analysis system can fairly be incorporated into domestic regimes, it may allow countries to construct a better mechanism that streamlines decision-making based on scientific evidence and public participation rather than yields to political interests.

The CPTPP risk analysis approach may provide momentum to rationalize and democratize national food safety regulatory regimes. However, it may also restrict importing countries' autonomy for food regulations, forcing them to stick to mainstream science-based standards normally evidenced in international agreements and practice. This article has argued that the extension

---

[157] *See* Ash & Lejarraga, *supra* note 22, at 76–77, 81 (arguing that the trend of RTA-plus, especially in the agricultural sector, is expected to be multilteralized, but conceding that it may be subject to political will).

of good faith technical and capacity-building support from developed parties and full commitments to regulatory cooperation may alleviate difficulties in compliance.